DATA EVALUATION RECORD

HYDROGEN PEROXIDE
($H_2ORANGE_2$ 126)

STUDY TYPE: ACUTE ORAL TOXICITY - RAT
[OPPTS 870.1100 (§81-1)] OECD 401
MRID 45746501

Prepared for
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Action No. K415

Primary Reviewer:
Susan Chang, M.S.
Signature: S Chang
Date: OCT 17 2002

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Signature: H T Borges
Date: OCT 17 2002

Robert H. Ross, M.S., Group Leader
Signature: Robert H. Ross
Date: OCT 17 2002

Quality Assurance:
Lee Ann Wilson, M.A.
Signature: L. A. Wilson
Date: OCT 17 2002

Disclaimer

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Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§ 81-1, 870.1100)

Product Manager: Marshall Swindell
Reviewer: Susan Chang
MRID No.: 45746501
Study Completion Date: January 10, 2002

Report No.: MB 01-9756.01

Testing Laboratory: MB Research Laboratories
Author: Daniel R. Cerven

GLP Compliance Statement (40 CFR §160.12): Included

Test Material: H_2 Orange$_2$ 126 (H_2O_2 = 1.34%), Lot No. 97980; cloudy liquid
Dosage: 5000 mg/kg

Species: Wistar rats (5 M and 5 F)
Weight: Males: 223-246 g, Females: 220-234 g **Age**: Approximately 7-11 weeks
Source: Ace Animals, Boyertown, PA

Summary:

1. **LD_{50} (mg/kg):** **Males** > 5000 mg/kg
   Females > 5000 mg/kg
   Combined > 5000 mg/kg
2. **The estimated LD_{50} is** > 5000 mg/kg.
3. **Tox. Category**: IV **Classification**: Acceptable

Procedure (Deviations from §81-1, 870.1100): None

Results:

Reported Mortality			
Dosage (mg/kg)[a]	(Number Deaths/Number Tested)		
	Males	Females	Combined
5000	0/5	0/5	0/10

Observations: All animals survived the study. Eight animals had normal body weight gains, but two females lost weight during the second week. Nine animals appeared normal throughout the study, but one male had alopecia on the left jawline on days 2 through 6.

Gross Necropsy Findings: Necropsy results were normal with the exception of one male that had liver abnormalities.

DATA EVALUATION RECORD

HYDROGEN PEROXIDE
($H_2ORANGE_2$ 126)

STUDY TYPE: ACUTE DERMAL TOXICITY - RABBIT
[OPPTS 870.1200 (§81-2)] OECD 402
MRID 45746502

Prepared for
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
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Prepared by
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DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2, 870.1200)

Product Manager: Marshall Swindell
MRID No.: 45746502

Reviewer: Susan Chang
Study Completion Date: January 10, 2002

Report No.: MB 01-9756.02

Testing Laboratory: MB Research Laboratories
Author: Daniel R. Cerven

GLP Compliance Statement (40 CFR §160.12): Included

Test Material: H_2 Orange$_2$ 126 (H_2O_2 = 1.34%), Lot No. 97980; cloudy liquid
Dosage: 5000 mg/kg

Species: New Zealand White rabbits (5M and 5F)
Weight: Males: 2.0-2.4 kg, Females: 2.0-2.3 kg **Age**: Approximately 13-14 weeks
Source: Sgarlat's Rabbitry, Harleysville, PA

Summary:

1. **LD_{50} (mg/kg)**: **Males** > 5000 mg/kg
   Females > 5000 mg/kg
   Combined > 5000 mg/kg
2. **The estimated LD_{50} is** > 5000 mg/kg.
3. **Tox. Category**: IV **Classification**: Acceptable

Procedure (Deviation From §81-2, 870.1200): No deviations were noted.

Results:

Reported Mortality			
Dosage (mg/kg)	(Number Deaths/Number Tested)		
	Males	Females	Combined
5000	0/5	0/5	0/10

Observations: All animals survived the study. Six animals had normal body weight gains, but two males and two females did not gain weight during the second week. All animals appeared normal throughout the study.

Gross Necropsy Findings: Necropsy results were normal with the exception of one male that had kidneys with clear fluid filled capsules.

DATA EVALUATION RECORD

HYDROGEN PEROXIDE
($H_2ORANGE_2$ 120)

STUDY TYPE: PRIMARY EYE IRRITATION - RABBIT
[OPPTS 870.2400 (§81-4)] OECD 405
MRID 45746503

Prepared for
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Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
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DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: Marshall Swindell
MRID No.: 45746503

Reviewer: Susan Chang
Study Completion Date: March 8, 2001

Report No.: MB 00-9008.04

Testing Laboratory: MB Research Laboratories
Author: Daniel R. Cerven

GLP Compliance Statement (40 CFR §160.12): Included

Test Material: H_2 $Orange_2$ 120; colorless liquid
Dosage: 0.1 mL

Species: New Zealand White rabbits (3F)
Weight: Females: 2.4-2.9 kg
Age: Approximately 4 months
Source: Sgarlat's Rabbitry, Harvey's lake, PA

Summary:

1. **Toxicity Category**: IV
2. **Classification**: Acceptable

Procedure (Deviations From §81-4, 870.2400): None

Results:

Observations	Number "Positive"/Number Tested			
	Hour			
	1	24	48	72
Corneal Opacity	0/3	0/3	0/3	0/3
Iritis	0/3	0/3	0/3	0/3
Conjunctivae				
Redness	0/3	0/3	0/3	0/3
Chemosis	1/3	0/3	0/3	0/3
Discharge	2/3	0/3	0/3	0/3

DATA EVALUATION RECORD

HYDROGEN PEROXIDE
($H_2ORANGE_2$ 120)

STUDY TYPE: SKIN SENSITIZATION - HUMAN
[OPPTS 870.2600 (§81-6)] OECD 406
MRID 45746504

Prepared for
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
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Primary Reviewer:
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DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)

Product Manager: Marshall Swindell
Reviewer: Susan Chang
MRID No.: 45746504
Study Completion Date: December 14, 2001

Report No.: ENV-8398

Testing Laboratory: Essex Testing Clinic, Inc., Verona, NJ
Author: Tracey Stavisky

GLP Compliance Statement (40 CFR §160.12): The study was conducted in compliance with the Principles of Good Clinical Practice (21 CFR Parts 50, 56, and 312) and the Declaration of Helsinki, and is consistent with 40 CFR 160 Good Laboratory Practice Standard and 40 CFR 26.

Test Material: H_2 Orange$_2$ 120 (ONE); white cloudy liquid
Positive Control Material: None

Species: Human (41 males and 184 females)
Weight: Not reported
Age: 18 to 69 years
Source: Not applicable

Method: Nine Repeated Insult (semi-occlusive) Patch Test (9-RIPT)

Summary:

1. **This product is not a human dermal sensitizer.**
2. **Classification:** Acceptable

Procedure (Deviation From §81-6, 870.2600): The study was conducted in accordance with the intent and purpose of Good Clinical Practice regulations described in Title 21 of the U.S. Code of Federal Regulations (CFR), the Declaration of Helsinki and/or Essex Testing Clinic (ETC) Standard Operating Procedures.

Procedure: The test material (approximately 0.2 mL) was applied to the back between the scapulae and waist area adjacent to the spinal midline with a 2×2 cm Webril pad backed by semi-occlusive surgical tape. The procedure was repeated every Monday, Wednesday, and Friday until nine applications had been made. The patch was removed 24 hours after application and scored 24 (prior to Wednesday and Friday applications) or 48 hours (prior to Monday application) later. If a mild dermal response was noted on any subject after induction, an adjacent site was used for the next application. If a mild dermal response occurred again, no further applications were made. After an approximately two week rest period, the subjects who remained in the study were challenged at a naive site. The site was scored 24 and 72 hours after application.

Results: Two hundred fourteen subjects completed the induction phase and 212 subjects completed the test procedure. Only one subject had a mild reaction at the application site after induction No. 5. No reaction was noted on any subject after challenge.